

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

This Document Relates To:

MDL No. 1:13-md-2419-RWZ

WILLIAM LEWIS and NANCY LEWIS, H/W

V.

NEW ENGLAND COMPOUNDING
PHARMACY, INC.;
AMERIDOSE, LLC;
ALAUNUS PHARMACEUTICAL, LLC;
NAZARETH HOSPITAL;
MERCY HEALTH SYSTEM;
WILLIAM A. ANDERSON, M.D.; and
THE ROTHMAN INSTITUTE a/k/a and/or d/b/a
THE ROTHMAN INSTITUTE AT NAZARETH
HOSPITAL

MDL No. 1:14-cv-10433-RWZ

JURY TRIAL DEMANDED

**MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS OF
DEFENDANTS, WILLIAM A. ANDERSON, M.D. AND THE ROTHMAN INSTITUTE
A/K/A AND/OR D/B/A THE ROTHMAN INSTITUTE AT NAZARETH HOSPITAL**

Defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, by and through their attorneys, O'Brien and Ryan, LLP, respectfully move this Honorable Court for partial judgment on the pleadings and, in support thereof, aver as follows:

1. On or about January 15, 2014, plaintiffs, William Lewis and Nancy Lewis, husband and wife, commenced the instant action by filing a Complaint in the Court of Common Pleas of Philadelphia County. A true and correct copy of plaintiff's Complaint is attached hereto as Exhibit "A."

2. In their pleadings, plaintiffs allege that, on September 25, 2012, defendant, William A. Anderson, M.D., administered a transforaminal epidural steroid injection at the L5 level of Mr. Lewis's spine. See Exhibit "A," para. 14.

3. Plaintiffs further contend that the steroid material injected in Mr. Lewis's back was developed, manufactured, compounded, marketed and sold by co-defendants, New England Compounding Pharmacy, Inc. a/k/a and/or d/b/a New England Compounding Center ("NECC"), Ameridose, LLC, and Alaunus Pharmaceutical, LLC. See Exhibit "A," para. 15.

4. In addition, plaintiffs maintain that, shortly after receiving the injection, Mr. Lewis developed a constant, sharp pain in his head, blurred vision and pain in both eyes. See Exhibit "A," para. 16.

5. Plaintiffs assert that they subsequently learned that the steroid material injected in Mr. Lewis's back was contaminated with aspergillus fumigatus and exserohilum and that NECC was recalling all its products due to fungal contamination. See Exhibit "A," paras. 17, 21-22, 26.

6. Plaintiffs allege that the steroid material injected in Mr. Lewis's back proximately caused him to suffer various severe and permanent injuries, including pain, mental anguish, anxiety and humiliation. See Exhibit "A," paras. 33-38.

7. Plaintiffs contend that moving defendants are liable for Mr. Lewis's injuries under theories of liability sounding in negligence, strict liability, breach of implied warranties and breach of express warranties. See Exhibit "A," Counts I-III, IX.

8. Plaintiffs also maintain that they are entitled to punitive damages from moving defendants. See Exhibit "A," Counts I-III, IX.

9. Furthermore, Mrs. Lewis asserts a claim against defendants for loss of consortium. See Exhibit "A," Count X.

10. On or about March 5, 2014, this matter was removed to the United States District Court for the Eastern District of Pennsylvania.

11. Thereafter, this case was transferred to this Court to be consolidated with other actions involving common questions of fact for coordinated or consolidated pre-trial proceedings under the caption set forth above.

12. On May 6, 2014, moving defendants filed an Answer with New Matter to plaintiffs' Complaint, denying all material allegations contained therein.

13. It is well-settled in Pennsylvania that healthcare providers cannot be held strictly liable under the Restatement (Second) of Torts § 402A for injuries caused by defects in products that are incidental to the provision of medical services. Cafazzo v. Central Med. Health Servs., 542 Pa. 526, 668 A.2d 521, 523-25 (1995).

14. Indeed, the Supreme Court of Pennsylvania has unequivocally held that plaintiffs may not maintain strict liability claims against healthcare providers, such as moving defendants, because healthcare providers do not constitute "sellers, providers, suppliers or distributors" of products under § 402A of the Restatement (Second) of Torts. Id. at 523-25.

15. In fact, the Supreme Court has stated that "on balance, the peculiar characteristics of medical services outweigh any of the reasons which might exist to assign strict liability in the medical setting." Id. at 527 (citing Hoven v. Kelble, 79 Wis.2d 444, 256 N.W.2d 379 (1977)).

16. Therefore, as plaintiffs are clearly barred as a matter of law from maintaining any strict products liability claims against moving defendants, this Court should enter judgment on the pleadings in moving defendants' favor on plaintiffs' products liability claim set forth in Count I of plaintiffs' Complaint.

17. Moreover, it is well-settled in Pennsylvania that the implied warranties of merchantability and fitness for a particular purpose do not apply to medical drugs and devices. Makripodis v. Merrell-Dow Pharm., Inc., 361 Pa. Super. 589, 523 A.2d 374, 377 (1987); Terrell v. Davol, Inc., 2014 WL 3746532, at *5-7 (E.D. Pa. July 30, 2014); Soufflas v. Zimmer, Inc., 474 F. Supp.2d 737, 751-52 (E.D. Pa. 2007).

18. Indeed, several Pennsylvania state and federal courts have recognized that “[t]he very nature of prescription medical products which are considered ‘unavoidably unsafe products’ precludes the imposition of a warranty of fitness for ‘ordinary purposes.’” Soufflas, 474 F. Supp.2d at 752 (quoting Taylor v. Danek Med., Inc., 1998 WL 962062, at *14 (E.D. Pa. Dec. 29, 1998)).

19. Likewise, these courts have refused to recognize an implied warranty of merchantability with respect to prescription medical drugs and devices, noting that “each individual for whom [medical products] are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient’s condition as well as the medical history of the patient.” Makripodis, 523 A.2d at 377.

20. Therefore, as plaintiffs are plainly barred as a matter of law from maintaining any claims for breach of implied warranties against moving defendants, this Court should enter judgment on the pleadings in moving defendants’ favor on plaintiffs’ breach of implied warranties’ claim set forth in Count II of plaintiffs’ Complaint.

21. Furthermore, “It is well-settled that punitive damages will lie only in cases of outrageous behavior, where [a] defendant’s egregious conduct shows either an evil motive or reckless indifference to the rights of others.” Castetter v. Mr. “B” Storage, 699 A.2d 1268, 1271 (Pa. Super. 1997) (citation omitted).

22. Indeed, the purpose of punitive damages is not to compensate the plaintiff for his injuries, but rather, to punish the defendant for outrageous conduct done in reckless disregard for another's rights and to deter similar conduct from occurring in the future. Schechter v. Watkins, 395 Pa. Super. 363, 577 A.2d 585, 595, allocatur denied, 526 Pa. 638, 584 A.2d 320 (1990) (citation omitted).

23. Punitive damages must be based on conduct that is malicious, wanton, reckless, willful or oppressive. Feld v. Merriam, 506 Pa. 383, 485 A.2d 742, 747-48 (1984).

24. Moreover, to determine if punitive damages are appropriate, the Court must examine “the act itself together with all the circumstances including the motive of the wrongdoers and the relations between the parties.” Id. at 748 (quoting Chambers v. Montgomery, 411 Pa. 339, 192 A.2d 355 (1963)).

25. In the instant matter, even a cursory review of plaintiffs' Complaint clearly indicates that plaintiffs have not alleged that Dr. Anderson engaged in any outrageous conduct that was malicious, wanton, reckless or oppressive. See Exhibit “A.”

26. Plaintiffs have also not pled facts that suggest that Dr. Anderson acted with an evil motive or with reckless disregard for Mr. Lewis's safety. See Exhibit “A.”

27. Rather, plaintiffs' Complaint merely alleges that Dr. Anderson injected Mr. Lewis with a contaminated steroid that was later recalled by the manufacturer, thereby causing him to suffer physical and mental pain and pecuniary loss. See Exhibit “A,” paras. 14-38.

28. Plaintiffs certainly do not allege that Dr. Anderson engaged in the sort of outrageous, evil conduct that warrants the imposition of punitive damages. See Exhibit “A.”

29. Therefore, since plaintiffs have clearly failed to plead sufficient facts to support a punitive damages claim against moving defendants and will not be able to produce any evidence

to support such a claim, this Court should enter judgment on the pleadings in moving defendants' favor on this claim.

WHEREFORE, for all the foregoing reasons, defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, respectfully request that this Honorable Court enter partial judgment on the pleadings in their favor and enter the proposed order attached hereto.

Respectfully submitted,

O'BRIEN & RYAN, LLP

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DATED: September 5, 2014

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING)	
PHARMACY, INC.)	
PRODUCTS LIABILITY LITIGATION)	MDL No. 1:13-md-2419-RWZ
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This Document Relates To:)	
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WILLIAM LEWIS and NANCY LEWIS, H/W)	
)	
v.)	
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NEW ENGLAND COMPOUNDING)	
PHARMACY, INC.;)	MDL No. 1:14-cv-10433-RWZ
AMERIDOSE, LLC;)	
ALAUNUS PHARMACEUTICAL, LLC;)	
NAZARETH HOSPITAL;)	
MERCY HEALTH SYSTEM;)	
WILLIAM A. ANDERSON, M.D.; and)	
THE ROTHMAN INSTITUTE a/k/a and/or d/b/a)	
THE ROTHMAN INSTITUTE AT NAZARETH)	JURY TRIAL DEMANDED
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Defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, by and through their attorneys, O'Brien and Ryan, LLP, respectfully move this Honorable Court for partial judgment on the pleadings and, in support thereof, submit the following Memorandum of Law.

I. MATTER BEFORE THE COURT

The Motion for Partial Judgment on the Pleadings of Defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital.

II. STATEMENT OF THE QUESTIONS INVOLVED

1. Whether this Court should enter judgment on the pleadings in favor of defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, on plaintiffs' products' liability claim because moving defendants do not constitute "sellers, providers, suppliers or distributors" of products under § 402A of the Restatement (Second) of Torts?

Suggested Answer: Yes.

2. Whether this Court should enter judgment on the pleadings in favor of defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, on plaintiffs' claim for breach of implied warranties because Pennsylvania does not recognize such claims with respect to prescription medical products as a matter of law?

Suggested Answer: Yes.

3. Whether this Court should enter judgment on the pleadings in favor of defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, on plaintiffs' punitive damages claim against them because plaintiffs have failed to plead sufficient facts to support such a claim?

Suggested Answer: Yes.

III. STATEMENT OF THE FACTS

On or about January 15, 2014, plaintiffs, William Lewis and Nancy Lewis, husband and wife, commenced the instant personal injury action against defendants by filing a Complaint in the Court of Common Pleas of Philadelphia County. See Exhibit "A." In their pleadings, plaintiffs allege that, on September 25, 2012, defendant, William A. Anderson, M.D., administered a transforaminal epidural steroid injection at the L5 level of Mr. Lewis's spine. See

Exhibit “A,” para. 14. Plaintiffs further contend that the steroid material injected in Mr. Lewis’s back was developed, manufactured, compounded, marketed and sold by co-defendants, New England Compounding Pharmacy, Inc. a/k/a and/or d/b/a New England Compounding Center (“NECC”), Ameridose, LLC, and Alaunus Pharmaceutical, LLC. See Exhibit “A,” para. 15. In addition, plaintiffs maintain that, shortly after receiving the injection, Mr. Lewis developed a constant, sharp pain in his head, blurred vision and pain in both eyes. See Exhibit “A,” para. 16. Plaintiffs assert that they subsequently learned that the steroid material injected in Mr. Lewis’s back was contaminated with aspergillus fumigatus and exserohilum and that NECC was recalling all its products due to fungal contamination. See Exhibit “A,” paras. 17, 21-22, 26. Plaintiffs allege that the steroid material injected in Mr. Lewis’s back proximately caused him to suffer various severe and permanent injuries, including pain, mental anguish, anxiety and humiliation. See Exhibit “A,” paras. 33-38.

Plaintiffs contend that moving defendants are liable for Mr. Lewis’s injuries under theories of liability sounding in negligence, strict liability, breach of implied warranties and breach of express warranties. See Exhibit “A,” Counts I-III, IX. Plaintiffs also maintain that they are entitled to punitive damages from moving defendants. See Exhibit “A,” Counts I-III, IX. Furthermore, Mrs. Lewis asserts a claim against defendants for loss of consortium. See Exhibit “A,” Count X.

On or about March 5, 2014, this matter was removed to the United States District Court for the Eastern District of Pennsylvania. Thereafter, this case was transferred to this Court to be consolidated with other actions involving common questions of fact for coordinated or consolidated pre-trial proceedings under the caption set forth above.

On May 6, 2014, moving defendants filed an Answer with New Matter to plaintiffs' Complaint, denying all material allegations contained therein. For the reasons set forth below, moving defendants now respectfully request the entry of partial judgment on the pleadings in their favor.

IV. **ARGUMENT**

A. Because Moving Defendants Are Not Sellers, Providers, Suppliers or Distributors of Products Pursuant to Section 402A of the Restatement (Second) of Torts as a Matter of Law, This Court Should Enter Judgment on the Pleadings in Moving Defendants' Favor on Plaintiffs' Products Liability Claim.

It is well-settled in Pennsylvania that healthcare providers cannot be held strictly liable under the Restatement (Second) of Torts § 402A for injuries caused by defects in products that are incidental to the provision of medical services. Cafazzo v. Central Med. Health Servs., 542 Pa. 526, 668 A.2d 521, 523-25 (1995). Indeed, the Supreme Court reached this precise holding nearly twenty (20) years ago in a case substantially similar to the instant matter.

Specifically, in Cafazzo v. Central Medical Health Services, 542 Pa. 526, 668 A.2d 521 (1995), the plaintiff-husband underwent surgery to implant a mandibular prosthesis and later discovered that the device was defective. Id. at 523. The plaintiffs subsequently commenced suit against the surgeon who implanted the prosthesis and the hospital where the operation took place, alleging that “‘all defendants sell, provide or use certain prosthetic devices,’ and that they should be held strictly liable as having ‘provided, sold or otherwise placed in the stream of commerce products manufactured by [the implant manufacturer].’” Id. The plaintiffs further maintained that the prosthesis was defectively designed, unsafe for its intended use, and lacked any warnings required to ensure its safe use. Id.

The healthcare provider defendants responded to the plaintiffs' Complaint by filing preliminary objections in the nature of a demurrer, arguing that the plaintiffs' strict liability claim was not cognizable under Pennsylvania law because the defendants were not "sellers" of the prosthesis under § 402A of the Restatement (Second) of Torts. Id. The trial court sustained the defendants' objections and dismissed the plaintiffs' strict liability claim. Id. The matter was later appealed to the Supreme Court of Pennsylvania. Id.

On appeal, the plaintiffs argued that they should be permitted to litigate their strict liability claims against the healthcare provider defendants because the surgeon and the hospital constituted "sellers" for purposes of § 402A of the Restatement (Second) of Torts. That section of the Restatement (Second) provides, in relevant part:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if:

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the consumer without substantial change in the condition in which it is sold.

Cafazzo, 668 A.2d at 523 (quoting Restatement (Second) of Torts § 402A). The plaintiffs further noted that the policy underlying the doctrine of strict products liability is "to insure that the costs of injuries resulting from defective products are borne by the manufacturers who put such products on the market rather than by the injured persons who are powerless to help themselves' and to further insure that defective products are removed from the market."

Cafazzo, 668 A.2d at 524 (quoting Shepard v. Alexian Bros. Hosp., 33 Cal. App.3d 606, 109 Cal. Rptr. 132 (1973)). Therefore, since the manufacturer of the mandibular prosthesis at issue was in bankruptcy and, thus, insolvent, the plaintiffs argued that the healthcare provider defendants

should be considered “sellers” under the Restatement (Second) to achieve the doctrine’s objectives. Cafazzo, 668 A.2d at 524.

However, the Supreme Court rejected the plaintiffs’ argument and held that neither the surgeon nor the hospital constituted “sellers, providers, suppliers or distributors of products” under § 402A. Id. at 524-25. In reaching this holding, the Court reasoned that “to ignore the ancillary nature of the association of product with activity is to posit surgery, or indeed any medical service requiring the use of a physical object, as a marketing device for the incorporated object.” Id. at 524. The Court then added that, “under such a theory, no product of which a patient in any medical setting is the ultimate consumer, from CT scanners to cotton balls, could escape the assignment of strict liability.” Id.

The Supreme Court further observed that the salient inquiry is, not on whether the healthcare providers charge a separate fee for the physical materials used in exercising medical skill, but, rather, what services are performed to restore or maintain the patient’s health. Id. Accordingly, the Court determined that

“[healthcare providers] could not be liable under a theory of strict liability because they were not in the business of selling the implant, its use was only incidental to [the healthcare providers’] primary function of providing medical services, and the medical services could not have been rendered without the use of this product.”

Id. at 524-25 (quoting Podrat v. Codman-Shurtleff, Inc., 384 Pa. Super. 404, 558 A.2d 895, allocatur denied, 524 Pa. 609, 569 A.2d 1368 (1989)). Thus, the Court reasoned that, while the mandibular implant was incidental to the plaintiff-husband’s surgery, it was “a necessary adjunct to the treatment administered, as were the scalpel used to make the incision, and any other material objects involved in performing the operation, all of which fulfill a particular role in [the] provision of medical service, the primary activity.” Cafazzo, 668 A.2d at 526. Consequently,

the Court held that neither the surgeon nor the hospital were considered “sellers, providers, suppliers or distributors of products” under § 402A. Id.¹

Applying the foregoing principles to the instant matter clearly reveals that plaintiffs are barred as a matter of law from maintaining any strict liability claims against moving defendants. Indeed, pursuant to its decision in Cafazzo v. Central Medical Health Services, 542 Pa. 526, 668 A.2d 521 (1995), the Supreme Court of Pennsylvania has unequivocally held that plaintiffs may not maintain strict liability claims against healthcare providers, such as moving defendants, because healthcare providers do not constitute “sellers, providers, suppliers or distributors” of products under § 402A of the Restatement (Second) of Torts. Id. at 523-25. In fact, the Supreme Court has stated that “on balance, the peculiar characteristics of medical services outweigh any of the reasons which might exist to assign strict liability in the medical setting.” Id. at 527 (citing Hoven v. Kelble, 79 Wis.2d 444, 256 N.W.2d 379 (1977)). Therefore, as plaintiffs are clearly barred as a matter of law from maintaining any strict products liability claims against moving defendants, this Court should enter judgment on the pleadings in moving defendants’ favor on plaintiffs’ products liability claim set forth in Count I of plaintiffs’ Complaint.

B. Because Pennsylvania Does Not Recognize Claims for Breach of Implied Warranties of Merchantability and Fitness for a Particular Purpose with Respect to Prescription Medical Products, This Court Should Enter Judgment on the Pleadings in Moving Defendants’ Favor on Plaintiffs’ Claim for Breach of Implied Warranties.

It is well-settled in Pennsylvania that the implied warranties of merchantability and fitness for a particular purpose do not apply to medical drugs and devices. Makripodis v.

¹ The Supreme Court alternatively rejected the plaintiffs’ request to expand the doctrine of strict liability to apply to healthcare providers, such as surgeons and hospitals, on the grounds that the policy reasons for imposing strict liability on manufacturers of products are not present in the context of a healthcare provider implanting or otherwise using a medical product while performing surgery. Id. at 525-27. “In short, medical services are distinguished by factors which make them significantly different in kind from the retail marketing enterprise at which 402A is directed.” Id. at 527.

Merrell-Dow Pharm., Inc., 361 Pa. Super. 589, 523 A.2d 374, 377 (1987); Terrell v. Davol, Inc., 2014 WL 3746532, at *5-7 (E.D. Pa. July 30, 2014); Doughtery v. C.R. Bard, Inc., 2012 WL 2940727, at *6-8 (E.D. Pa. July 18, 2012); Soufflas v. Zimmer, Inc., 474 F. Supp.2d 737, 751-52 (E.D. Pa. 2007). These warranties arise by operation of law and were created to protect consumers from the harmful effects of products sold below commercial standards or which are unfit for the buyer's purposes. Soufflas, 474 F. Supp.2d at 751-52 (citing Altronics of Bethlehem, Inc. v. Repco, Inc., 957 F.2d 1102, 1105 (3d Cir. 1992)). The essence of the implied warranty of merchantability is that the product sold is fit for the ordinary purposes for which such goods are used. Terrell, 2014 WL 3746532, at *6. Accord 13 Pa. C.S.A. § 2314(b)(3). The implied warranty of fitness for a particular purpose, on the other hand, requires the seller of a product to know the particular purpose for which such goods are required and the buyer to rely on the seller's skill and judgment to select and furnish appropriate goods. Soufflas, 474 F. Supp.2d at 752. Accord 13 Pa. C.S.A. § 2315.

However, several Pennsylvania state and federal courts have recognized that “[t]he very nature of prescription medical products which are considered ‘unavoidably unsafe products’ precludes the imposition of a warranty of fitness for ‘ordinary purposes.’” Soufflas, 474 F. Supp.2d at 752 (quoting Taylor v. Danek Med., Inc., 1998 WL 962062, at *14 (E.D. Pa. Dec. 29, 1998)). Likewise, these courts have refused to recognize an implied warranty of merchantability with respect to prescription medical drugs and devices, noting that “each individual for whom [medical products] are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient.” Makripodis, 523 A.2d at 377.²

² The United States District Court for the Eastern District of Pennsylvania has further concluded that the same policy considerations that preclude strict liability claims involving medical devices also apply to breach of implied

Applying the foregoing principles to the instant matter clearly reveals that plaintiffs are precluded as a matter of law from pursuing any claims for breach of implied warranties against moving defendants. Indeed, as the foregoing authorities make clear, Pennsylvania does not recognize claims for breach of the implied warranties of merchantability and fitness for a particular purpose with respect to prescription medical products. Therefore, as plaintiffs are plainly barred as a matter of law from maintaining any claims for breach of implied warranties against moving defendants, this Court should enter judgment on the pleadings in moving defendants' favor on plaintiffs' breach of implied warranties' claim set forth in Count II of plaintiffs' Complaint.

C. Because Plaintiffs Have Failed To Plead Sufficient Facts To Support a Punitive Damages Claim Against Moving Defendants, This Court Should Enter Judgment on the Pleadings in Moving Defendants' Favor on Plaintiffs' Punitive Damages Claim.

"It is well-settled that punitive damages will lie only in cases of outrageous behavior, where [a] defendant's egregious conduct shows either an evil motive or reckless indifference to the rights of others." Castetter v. Mr. "B" Storage, 699 A.2d 1268, 1271 (Pa. Super. 1997) (citation omitted). Accord Phillips v. Cricket Lighters, 584 Pa. 179, 883 A.2d 439, 445 (2005); Hutchison v. Luddy, 582 Pa. 114, 870 A.2d 766, 770 (2005); Feld v. Merriam, 506 Pa. 383, 485 A.2d 742, 747 (1984). Indeed, the purpose of punitive damages is not to compensate the plaintiff for his injuries, but rather, to punish the defendant for outrageous conduct done in reckless disregard for another's rights and to deter similar conduct from occurring in the future. Hutchison, 870 A.2d at 770; Kirkbride v. Lisbon Contractors, Inc., 521 Pa. 97, 555 A.2d 800, 803 (1989); Schechter v. Watkins, 395 Pa. Super. 363, 577 A.2d 585, 595, allocatur denied, 526 Pa. 638, 584 A.2d 320 (1990). Thus, neither mere negligence, nor even gross negligence,

warranty claims and counsel against imposing liability for injuries caused by medical products pursuant to an implied warranty theory. Terrell, 2014 WL 3746532, at *7; Doughtery, 2012 WL 2940727, at *8.

indicates sufficient culpability to justify an award of punitive damages. Phillips, 883 A.2d at 445; Castetter, 699 A.2d at 1271-72. Rather, punitive damages must be based on conduct that is intentional, willful, wanton or reckless. Phillips, 883 A.2d at 446; Feld, 485 A.2d at 747-48.

Of course, it is the function of the trial court to initially determine whether the plaintiff has presented sufficient evidence to support a punitive damages claim. Rizzo v. Michener, 401 Pa. Super. 47, 584 A.2d 973, 979 (1990), allocatur denied, 528 Pa. 613, 596 A.2d 159 (1991) (citing Martin v. Johns-Manville Corp., 508 Pa. 154, 494 A.2d 1088 (1985) (plurality opinion), abrogated on other grounds by Kirkbride v. Lisbon Contractors, Inc., 521 Pa. 97, 555 A.2d 800, 801 (1989)). To determine if punitive damages are appropriate, the Court must examine “the act itself together with all the circumstances including the motive of the wrongdoers and the relations between the parties.” Feld, 485 A.2d at 748 (quoting Chambers v. Montgomery, 411 Pa. 339, 192 A.2d 355 (1963)). In making this assessment, “[t]he state of mind of the actor is vital.” Hutchison, 870 A.2d at 770 (quoting Feld, 485 A.2d at 748). “The act, or the failure to act, must be intentional, reckless or malicious.” Hutchison, 870 A.2d at 770 (quoting Feld, 485 A.2d at 748). Thus, a punitive damages award in Pennsylvania “must be supported by evidence sufficient to establish that (1) a defendant had *a subjective* appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in *conscious disregard* of that risk.” Hutchison, 870 A.2d at 772 (emphasis added) (citing Martin, 494 A.2d at 1097-98).

Consequently, the Supreme Court of Pennsylvania has characterized punitive damages as an “extreme remedy” to be available only in the most exceptional matters in which a defendant has acted in a fashion which is particularly egregious. Phillips, 883 A.2d at 445-46. “Such a punishment should not be meted out to every defendant who is found to have acted negligently;

rather it should be reserved for those cases in which the defendant has acted in a particularly outrageous fashion.” Id. at 446. See Gallagher v. Temple Univ. Hosp., 2005 WL 2649868 (Pa. Super. 2005) (holding that the defendant’s conduct in altering medical records to conceal the plaintiff’s oxygen deprivation could not support a punitive damages award because the defendant’s conduct was independent from the malpractice upon which liability was based), rev’d on other grounds, 587 Pa. 508, 901 A.2d 981 (2006); Mancini v. Yavorek, 61 D. & C.4th 1 (Northumberland Co. 2003) (holding that a plaintiff who was injured by surgical sponges left in her pelvic region following an operation could not recover punitive damages from a surgeon who dictated an operative note indicating that all sponge and instrument counts were proper despite receiving an x-ray report showing the presence of a foreign object in the plaintiff’s pelvis). Compare with Guernsey v. County Living Personal Care Home, Inc., 2006 WL 1412765 (M.D. Pa. 2006) (holding that punitive damages could be recovered from nursing home officials who permitted a resident to have access to the room of an elderly Alzheimer’s patient where he repeatedly raped her even though the nursing home officials were aware that the resident had prior convictions for sex offenses and had sexually harassed the nursing home staff); Lawrence v. Kunkle, 75 D. & C.4th 370 (Lancaster Co. 2005) (holding that a patient could maintain a punitive damages claim against a surgeon who refused to perform emergency surgery on the patient because the patient did not have medical insurance even though the surgeon knew that the patient would likely suffer permanent neurological and functional damage if the operation was delayed). Accordingly, the Superior Court of Pennsylvania has instructed that

since the purpose of punitive damages is not compensation of the plaintiff but punishment of the defendant and deterrence, *these damages can be awarded only for conduct for which this remedy is appropriate – which is to say, conduct involving some element of outrage similar to that usually found in crime.*

Rizzo, 584 A.2d at 979 n.7 (emphasis in the original) (quoting Restatement (Second) of Torts § 908, comment b).³

In Feld v. Merriam, 506 Pa. 383, 485 A.2d 742 (1984), the Supreme Court of Pennsylvania discussed the character of offense which is sufficiently outrageous to warrant the imposition of punitive damages. In Feld, the plaintiffs, a husband and wife, were abducted at gunpoint while they were parking their car in a parking garage owned by the apartment complex where they lived. Id. at 744. The criminals forced the couple to the back seat of their car and drove unimpeded past the guard on duty at the exit gate. Id. After leaving the premises, the felons drove to a remote location, where they sexually assaulted the wife. Id.

The plaintiffs brought suit against several defendants, including the owners of the apartment complex. Id. at 744-45. The plaintiffs alleged, *inter alia*, that their landlord owed them a duty of protection and breached that duty, thereby causing them to suffer grievous injuries. Id. Following an eight-day trial, a jury returned a verdict in the plaintiffs' favor and awarded them substantial compensatory and punitive damages. Id. at 745. The defendants then filed an appeal to the Superior Court of Pennsylvania, arguing, *inter alia*, that the evidence failed to support the jury's punitive damages award. Id. at 745-47. After the Superior Court affirmed the entry of judgment in the plaintiffs' favor,⁴ the Supreme Court of Pennsylvania granted the defendants' petition for allowance of appeal. Id. at 745.

The Supreme Court reversed the Superior Court's decision and remanded the matter to the lower court for a new trial. Id. at 745-48. In reaching this decision, the Supreme Court concluded that the record was insufficient, as a matter of law, for a jury to conclude that the

³ The Supreme Court of Pennsylvania has adopted the Restatement (Second) of Torts § 908 as the law of Pennsylvania. Feld v. Merriam, 506 Pa. 383, 485 A.2d 742, 747 (1984); Chambers v. Montgomery, 411 Pa. 339, 192 A.2s 355, 358 (1963).

⁴ The Superior Court reduced the award of punitive damages to the plaintiff-husband, but affirmed the trial court's entry of judgment in the plaintiffs' favor in all other respects. Id. at 745.

defendants' conduct was outrageous. Id. at 748. The Court explained that, in deciding whether to impose punitive damages against a tortfeasor, a court should not consider a third party's criminal conduct or the plaintiffs' injuries, regardless of how outrageous they may be. Id. Rather, the Supreme Court stressed that a trial court should examine only the tortfeasor's conduct in determining whether punitive damages are warranted. Id. The Court then held that the defendants did not possess the requisite state of mind to impose punitive damages against them for the injuries suffered by the plaintiffs. Id. According to the Court, "[w]hile the record indicates that the security systems might have been inadequate under the circumstances, there was no evidence of an evil motive or a reckless indifference to the safety of the tenants." Id. Therefore, the Supreme Court concluded that there was insufficient evidence to support a punitive damages award against the defendants. Id.

More recently, in Hutchison v. Luddy, 582 Pa. 114, 870 A.2d 766 (2005), the Supreme Court of Pennsylvania re-examined the standard governing the awarding of punitive damages in Pennsylvania. The specific question before the Court was whether a negligent supervision claim under section 317 of the Restatement (Second) of Torts can support an award of punitive damages. Id. at 769. The Court ultimately concluded that the law does not proscribe a plaintiff from pursuing punitive damages in connection with a section 317 claim where the facts so warrant. Id. at 773. However, in reaching this conclusion, the Court again stressed the limited circumstances under which such damages are available. Id. at 770-73.

Specifically, the Supreme Court re-iterated that "punitive damages are penal in nature and are proper *only* in cases where the defendant's actions are so outrageous as to demonstrate willful, wanton or reckless conduct." Id. at 770 (emphasis added) (citing SHV Coal, Inc. v. Continental Grain Co., 526 Pa. 489, 587 A.2d 702, 704 (1991); Feld, 485 A.2d at 747-48;

Chambers v. Montgomery, 411 Pa. 339, 192 A.2d 355, 358 (1963); Restatement (Second) of Torts § 908, comment b). The Court also emphasized that, when determining whether punitive damages should be imposed, the actor's state of mind is "vital" as "[t]he act, or the failure to act, must be intentional, reckless or malicious." Hutchison, 870 A.2d at 770 (quoting Feld, 485 A.2d at 748). The Court then explained the requisite state of mind that a tortfeasor must possess to support a punitive damages claim based on "reckless indifference," stating that it is "'where the 'actor knows, or has reason to know, . . . of facts which create a high degree of risk of physical harm to another, and deliberately proceeds to act, or to fail to act, in conscious disregard of, or indifference to, that risk.'"' Hutchison, 870 A.2d at 771 (quoting Martin, 494 A.2d at 1097 (quoting Restatement (Second) of Torts § 500, Comment a)). "In other words, . . . 'an appreciation of the risk of harm is a necessary element of the mental state required for the imposition of punitive damages.'" Hutchison, 870 A.2d at 771 (quoting Martin, 494 A.2d at 1097, n.12). The Court further observed:

"The only purpose of punitive damages is to deter outrageous conduct. It is impossible to deter a person from taking risky action if he is not conscious of the risk. . . . [T]he Restatement explains that 'reckless indifference to the rights of others and conscious action in *deliberate* disregard of them . . . may provide the necessary state of mind to justify punitive damages.' . . . Therefore, an appreciation of the risk is a necessary element of the mental state required for the imposition of such damages."

Hutchison, 870 A.2d at 771-72 (emphasis in the original) (quoting Martin, 494 A.2d at 1097, n.12 (quoting Restatement (Second) of Torts § 500, Comment b)). Consequently, the Court held that punitive damages can only be assessed if a plaintiff demonstrates that (1) the defendant had *a subjective appreciation* of the risk of injury to which the plaintiff was subjected *and* that (2) the defendant acted, or failed to act, in *conscious disregard* of that risk. Hutchison, 870 A.2d at 772 (citing Martin, 494 A.2d at 1097-98).

In 2002, the Pennsylvania Legislature codified the standards for recovering punitive damages in medical malpractice cases when it enacted the Medical Care Availability and Reduction of Error (MCARE) Act, 40 P.S. § 1303.505. The statute specifically provides that “[p]unitive damages may be awarded for conduct that is the result of the health care provider’s willful or wanton conduct or reckless indifference to the rights of others.” 40 P.S. § 1303.505(a). The Act further stresses that “[a] showing of gross negligence is insufficient to support an award of punitive damages.” 40 P.S. § 1303.505(b).

Applying the foregoing principles to the instant matter clearly reveals that plaintiffs have failed to plead sufficient facts to support a claim for punitive damages against moving defendants. Indeed, plaintiffs certainly have not pled any facts that suggest that Dr. Anderson engaged in any egregious conduct that was intentional, willful, wanton or reckless. Plaintiffs also have not claimed in their pleadings that Dr. Anderson acted with an evil motive or with deliberate disregard for Mr. Lewis’s safety. Rather, plaintiffs merely allege that Dr. Anderson injected Mr. Lewis with a contaminated steroid that was later recalled by the manufacturer, thereby causing him to suffer physical and mental pain and pecuniary loss. See Exhibit “A,” paras. 14-38. This clearly is not the sort of outrageous, evil conduct that warrants the imposition of punitive damages. Moreover, plaintiffs certainly have not averred that Dr. Anderson was motivated by some improper purpose in treating Mr. Lewis or that he consciously disregarded Mr. Lewis’s safety with a subjective appreciation of the patient’s risk of harm.

Indeed, this is not a case where Dr. Anderson refused to provide emergent medical care to a patient or allowed an untrained medical student to perform a complex operation without the supervision of a licensed surgeon. This is also not a case where a resident repeatedly endangered patients by providing substandard treatment, but Dr. Anderson continued to allow him to practice

medicine. Moreover, this certainly is not a case where Dr. Anderson engaged in outrageous conduct “similar to that usually found in a crime.” Rizzo, 584 A.2d at 979 n.7. Furthermore, there is absolutely no assertion that Dr. Anderson subjectively understood that Mr. Lewis was exposed to an unreasonable risk of injury when he treated the patient at Nazareth Hospital, much less that he consciously disregarded any such risk.

The Supreme Court of Pennsylvania has emphasized that punitive damages are an extreme remedy which should only be assessed in the most egregious circumstances. Phillips, 883 A.2d at 445-46. The foregoing authorities manifest that the level of transgression which warrants the imposition of punitive damages is an offense so outrageous that it parallels criminal misconduct. Rizzo, 584 A.2d at 979 n.7. Plaintiffs can receive sufficient redress for any injuries caused by a tortfeasor’s negligence by seeking an award of compensatory damages. However, when punitive damages are “[i]mposed indiscriminately, . . . they have a devastating potential for harm.” State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 123 S. Ct. 1513, 1523 (2003) (quoting Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 111 S. Ct. 1032 (1991) (O’Connor, J., dissenting)).

Instantly, plaintiffs certainly cannot demonstrate that Dr. Anderson acted in an outrageous manner or with deliberate indifference to Mr. Lewis’s welfare, much less that his conduct approached criminal misconduct. Consequently, since plaintiffs have clearly failed to plead sufficient facts to support a punitive damages claim against moving defendants and will not be able to produce any evidence to support such a claim, this Court should enter judgment on the pleadings in moving defendants’ favor on this claim.

V. CONCLUSION

For all the foregoing reasons, defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, respectfully request that this Honorable Court enter partial judgment on the pleadings in their favor and enter the proposed order attached hereto.

Respectfully submitted,

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at Nazareth Hospital

DATED: September 5, 2014

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

This Document Relates To:

MDL No. 1:13-md-2419-RWZ

WILLIAM LEWIS and NANCY LEWIS, H/W

V.

NEW ENGLAND COMPOUNDING
PHARMACY, INC.;
AMERIDOSE, LLC;
ALAUNUS PHARMACEUTICAL, LLC;
NAZARETH HOSPITAL;
MERCY HEALTH SYSTEM;
WILLIAM A. ANDERSON, M.D.; and
THE ROTHMAN INSTITUTE a/k/a and/or d/b/a
THE ROTHMAN INSTITUTE AT NAZARETH
HOSPITAL

MDL No. 1:14-cv-10433-RWZ

JURY TRIAL DEMANDED

ORDER

AND NOW, this day of 2014, upon consideration of the Motion for Partial Judgment on the Pleadings of Defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, and any response thereto, it is hereby ORDERED and DECREED that Moving Defendants' Motion is GRANTED and the following claims are stricken from plaintiffs' Complaint:

1. Plaintiffs' Products Liability Claim Against Defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, set forth in Count I of plaintiffs' Complaint;

2. Plaintiffs' Breach of Implied Warranties' Claim Against Defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital, set forth in Count II of plaintiffs' Complaint; and

3. Plaintiffs' Claim for Punitive Damages Against Defendants, William A. Anderson, M.D. and The Rothman Institute a/k/a and/or d/b/a The Rothman Institute at Nazareth Hospital.

BY THE COURT:

J.